



VIA MED

Pulse Oximeter VM2105 Finger SpO₂

Finger oximeter for monitoring of functional arterial oxygen saturation (SpO₂) and pulse rate,

Class IIb

NBOG MD1302

Carried out by Derek Lamb
17 / 03 / 15



VIA MED

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Stock References Review

Stock Reference	Description
0012103	Finger Pulse Oximeter Viamed VM 2103.
0012105	Finger Pulse Oximeter Viamed VM 2105.
0012106	Finger Pulse Oximeter Viamed VM 2105.

Comments on Stock references review:

part number up to date

Supplier Review

Stock Reference	Description	Supplier A/C	Supplier P/N	Supplier Name	Rating
0012103	Finger Pulse Oximeter V	00009300		Bluepoint Medical	A
0012105	Finger Pulse Oximeter V	00009300	2020112003	Bluepoint Medical	A
0012106	Finger Pulse Oximeter V	00009300		Bluepoint Medical	A

Comments on Suppliers:

Supplier review up to date,

Sales Information

Stock Reference	Description	2009	2010	2011	2012	2013	2014	2015
0012103	Finger Pulse Oximeter V				15	54	45	2
0012105	Finger Pulse Oximeter V	174	151	367	242	91	57	14
0012106	Finger Pulse Oximeter V	221	57	26	20	37	23	

Comments on Sales Information:

units still selling

Countries Review

Country	2009	2010	2011	2012	2013	2014	2015
AU Austria	[X]				[X]	[X]	
B Belgium	[X]	[X]	[X]		[X]		
CAN Canada	[X]						
CI Canary Islands			[X]				
CY Cyprus			[X]			[X]	
CZ Czech Republic	[X]		[X]	[X]	[X]		
DE Denmark	[X]		[X]				
EG Egypt	[X]		[X]				
ES Estonia		[X]	[X]		[X]	[X]	
F France	[X]	[X]			[X]	[X]	
FI Finland	[X]	[X]	[X]	[X]	[X]	[X]	
G Germany							
GR Greece	[X]						
IND Indonesia					[X]		
IQ IRAQ				[X]			
IRE Ireland					[X]		
IS Israel	[X]		[X]				
IT Italy					[X]		
J Japan	[X]			[X]			
KE Kenya		[X]					
KU Kuwait			[X]				
LEB Lebanon				[X]			
NE Netherlands	[X]						
NO Norway	[X]	[X]	[X]	[X]	[X]	[X]	
OM Oman	[X]	[X]			[X]	[X]	
P Poland	[X]				[X]	[X]	
PO Portugal	[X]	[X]	[X]				
SA South Africa			[X]	[X]			
SAU Saudi Arabia		[X]	[X]		[X]		
SI Singapore	[X]						
SL Slovenia		[X]					
SP Spain	[X]	[X]	[X]				
SW Sweden			[X]				
SWI Switzerland	[X]	[X]	[X]	[X]	[X]	[X]	[X]
TH Thailand	[X]		[X]				
UAE U A E	[X]	[X]					
UK United Kingdom	[X]	[X]	[X]	[X]	[X]	[X]	[X]
USA USA				[X]			

Comments on Sales to Countries:

units still selling in multiple countries

Comments on Risks with Sales to Countries:

no new countries sold to in last couple of years
no risks identified

Returns Review

Stock Reference	Fault	2009	2010	2011	2012	2013	2014	2015
0012103	False reading				3			
0012105	Battery lead fault			14			1	
0012105	Dead		2		3			
0012105	Display fault			2		1	1	
0012105	False reading	1	1	3				
0012105	Faulty Electronics	1						
0012105	Faulty probe	1	4	1				
0012105	High reading			3				
0012105	Intermittent	1	1	1				
0012105	Intermittent When Squeezed		2					
0012105	No Fault Found		1	2				
0012105	No Fault Return to Stock		1					
0012105	Picking up false signal	1						
0012105	Rewired		1					
0012105	TEST		1					
0012105	Tested OK			2				
0012105	Unchecked - Returned to Stock							
0012105	Unit dead	1						
0012106	Battery lead fault		2	3				
0012106	Battery wires broken					1		
0012106	Case fault		1					
0012106	Dead		3		2			
0012106	Display fault		1					
0012106	False reading	2	8	1	3	1		
0012106	Faulty Electronics	1						
0012106	Faulty probe		2	1				
0012106	High reading			1				
0012106	Intermittent When Squeezed		1					
0012106	Orange VM2105 problem		12					
0012106	Picking up false signal		1					
0012106	TEST	1	1					
0012106	Unable to switch on		1					
0012106	Uneconomical to repair		1					

Comments on Returns:

Very Low returns,

Comments on Risks with Returns and Potential Re-work:

n/a

Design Changes Review

Showing Documents Filed in Y 14 Design Changes

Comments on Design Changes:

no design changes have taken place

Comments on Risks with Design Changes:

n/a

User Instructions Review

Showing Documents Filed in F 5 User Instructions

Document ID	Description	Date Added/Updated
6976	VM 2105 Instruction Manual Spanish	17/03/10
6975	VM 2105 Instruction Manual German	17/03/10
6974	VM 2105 Instruction Manual French	17/03/10
6973	VM 2105 Instruction Manual English	17/03/10
5080	VM-2105 Finger Oximeter Quick Start Guide Document	17/02/09

Comments on User Instructions:

no changes to the user manual.

Comments on Risks User Instructions:

no risks identified.

Labels Review

Showing Documents Filed in F 7 / F 8 Labels

Comments on Labels:

no changes to the labels

Comments on Risks Labels:

no risks identified

Documentation Updates / Changes

Document ID	Description	Date Added/Updated
14602	BPM Annex II BPM Notified body certification Blue Point EC Certi...	10/12/14
14042	Pulse Oximeter VM2105 Finger SpO2 External Test Results drop t...	09/06/14
13273	Pulse Oximeter VM2105 Finger SpO2 Post Market Surveillance	16/01/14

Comments on Document Changes:

Updated certificate,
added test results of the drop tests
no other document changes

Comments on Risks with Document Changes:

no risk identified.

Internal Issues Review

Number of Issues reviewed: 25

Issue ID	Subject
51371	Returned Items SOR599
46241	GHX/Peto exporter - image links
48633	test
45586	Yorkshire Ambulance consignment stock levels
55949	VM201, 2103 & 2105
55790	Finger Pulse Oximeters Feedback - MD300 - P/N: 2810011
47814	Ingress Protection Rating - Water Ingress
47813	Ingress Protection Rating - Water Ingress
47812	Ingress Protection Rating - Water Ingress
47811	Ingress Protection Rating - Water Ingress
47810	Ingress Protection Rating - Water Ingress
47809	Ingress Protection Rating - Water Ingress
47808	Ingress Protection Rating - Water Ingress
47807	Ingress Protection Rating - Water Ingress
47806	Ingress Protection Rating - Water Ingress
47805	Ingress Protection Rating - Water Ingress
47804	Ingress Protection Rating - Water Ingress
47803	Ingress Protection Rating - Water Ingress
47802	Ingress Protection Rating - Water Ingress
47800	Ingress Protection Rating - Water Ingress
47799	IPXX Ratings - Ingress Protection
47798	IPXX Ratings - Ingress Protection
47797	IPXX Ratings - Ingress Protection
50479	Drop tests: 0012101, 0012103, 0012105, 0012106
51985	Finger Oximeters - R.H. Specification Update

Comments on Issues:

No concerns raised in the issues system,
stocking issues, prices issues mainly
updated information to staff regarding IPx ratings.

Comments on Risks with Issues:

no risks identified in the issues system

Clinical / FDA Incidents online search

Clinical Investigation online review

Do any of the Results indicate a Risk / Problem : No
Do any of the Results indicate outdated Technology : No
Comments on Clinical Search :

SpO2 used globally

Review of online FDA Incident reports

Do any of the Results indicate a Risk / Problem : Yes
Do any of the Results indicate outdated Technology : No
Comments on Clinical Search :

57387

Risk Search Yes

Out of Date Search No

SpO2 used globally, no specific reports found

Found a recall FDA Z-0213-2015 , relating to masimo cables,
supplied in the USA and Portica.

note of recall:

Firm has identified a small number of Oximetry Cables with crossed -internal wires. The effect on
performance when these

wires are crossed is that when a low SpO2 value is measured, a high SpO2 value would be displayed on the
monitoring

device. Additionally when a high SpO2 value is measured, a low SpO2 value would be displayed on the
monitoring device.

Risk ISO 14971 : 2012 Review

Full ISO 14971 : 2012 Risk review held off-site at original OEM company